

# APPLICATION NOTE

## MULTI LOCATION MICROBIAL AIR SAMPLING

**SAMPLING**  
**N. 676**  
**JULY 2006**

APPLICATION NOTE

### Introduction

It is suggested the sampling of bio-aerosol in Clean Room and isolator is performed in different positions / locations. Space and transfer of instruments are the main concerns for the Operation Manager in this premises and it is for these reasons that International pbi developed and produced the "SAS Isolator" and the "ML-SAS" (Multi Location).



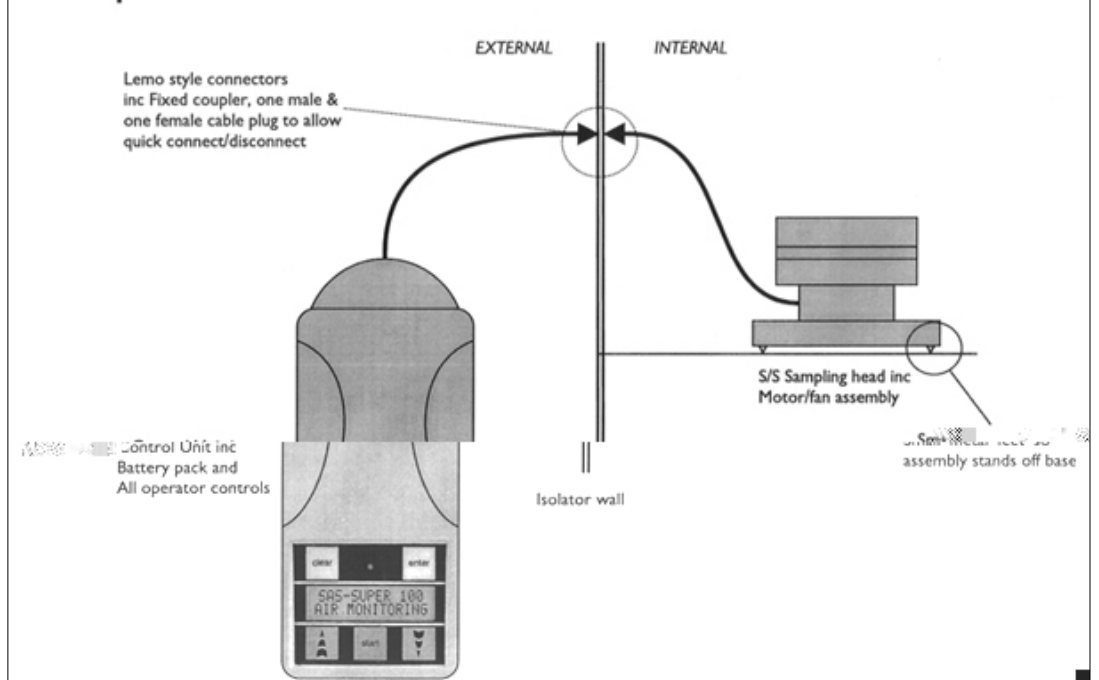
### Principle of "SAS Isolator"

The method is the classic well known "Surface Air System" by impact on agar surface. The AISI stainless steel aspirating chamber + aspirating head of the sampler are completely separated from the body of the instrument and connected by a cable. Aspirating chamber + aspirating head are inside the Clean Room or the isolator; the body of the air sampler is outside and acts as "controller".

The "SAS Isolator" may use AISI a "Drilled" stainless steel aspirating head or a "Dispo Head" sterile, certified, disposable aspirating head.

Sas Super Isolator – Code: 43216

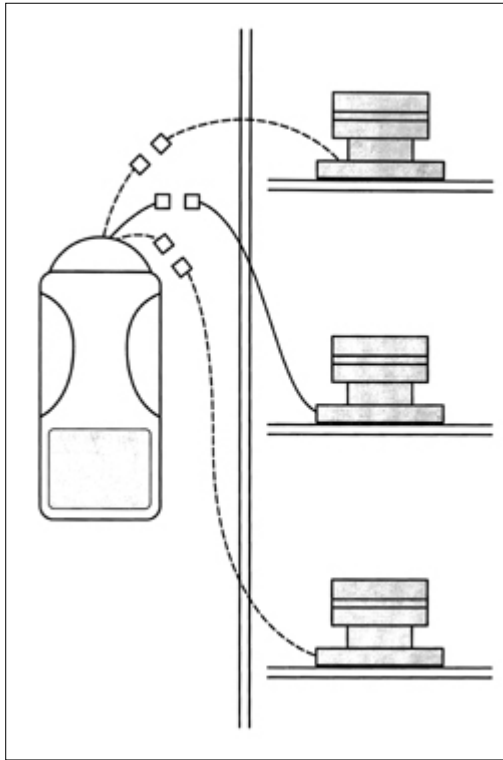
### SAS Super Isolator Schematic



## □ The “ML-SAS” (Multi Location)

Several AISI stainless steel aspirating heads and aspirating chambers can be positioned and/or fixed in different locations of the premises or isolator. Each aspirating chamber is connected by cable to a single body of the air sampler. All the sampling data are memorised by the electronics of the air sampler and transferred to a P.C. or printer for recording.

Each s/s aspirating chamber is connected to the main controller unit by a cable of 25 metres.



## □ PROCEDURE OPERATIVE STANDARD

### - OBJECT

The use of “ML-SAS” multi location microbial air sampler in Clean Room and / or isolator

### - PURPOSE

A regular programmed monitoring of the environment to evaluate the bio – aerosol, avoiding possible cross-contamination and instrument transfer in critical areas

### - RESPONSIBILITY

Plant Manager in close co-operation with Laboratory Manager

### - STANDARD

Guidelines as specified in ISO-14698

### - GLOSSARY

Air Flow, Air Sampler, Bacteria, Battery pack, Bio – aerosol, Bioburden, Calibration, Calibration Certificate, CFU, Colony Forming Unit, Micro-organism, Validation.

### - MATERIAL

- “SAS Super Isolator” microbiological air samplers (suitable for 55 mm Contact plate or 90 mm Petri dish) Code: 43219
- “ML-SAS” aspirating chamber for Contact plate, complete of connecting cable (it is suggested the possible connection up to 12 units) Code: 87085
- “Dispo Head” sterile certified plastic resin aspirating head for Contact plate Code: 86996 or/and
- “Drilled” stainless steel aspirating head for Contact plate Code: 15503
- “Swift” Battery charger
- Fresh prepared irradiated Contact plate or 90 mm Petri dish (triple packing) with Tryptic Soy Agar

-“Pyramid” System for air flow rate monitoring at regular intervals

-Plastic bags for removal of used material

-Instruction Manual

## - PROTOCOL

### Installation

1. The several aspirating chambers should be connected according to the scheme.
2. The aspirating chambers should be positioned as close as possible to the more critical areas of the Clean Room or isolator and to avoid any interference with the operating activity and any disruption of the sterile air flow.
3. The main body of the air sampler, acting as a control unit, should be positioned in a convenient place, outside the Clean Room or the isolator, to facilitate the sampling command.

### Operation

4. The sterile Contact plates (or Petri dishes) containing the agar medium are transferred inside the isolator (or the Clean Room) in their sterile original package.
5. The steam sterilised “Drilled” aspirating heads or the sterile disposable “Dispo Head” are transferred inside the isolator (or the Clean Room) in their sterile original package.
6. The Contact plate (or Petri dish) are taken out from their package and inserted into the chamber of the air sampler. The lid of the plate is aseptically removed and transferred to a sterile bag (or container).
7. The sterilised s/s or sterile disposable aspirating head is removed from its package and applied to the aspirating chamber.
8. The suggested volume of air to be aspirated for each cycle is 1000 litres (1 cubic metre). This volume may be aspirated continuously on the same plate or progressively in separate cycles (e.g.: at ten or 20 minute intervals).
9. The test should be repeated every hour (or at different interval time depending from the available statistical data).
10. The Contact plate (or Petri dish) should be removed at the end of each aspirating cycle; the lid of the plate is applied; the plate is re-introduced in its original bag. It will then transferred to the incubator (32°C or 37°C).
11. The sampling data should be printed connecting the port of the air sampler to a printer or P.C.
12. The same operation (from 4 to 11) should be repeated for each sampling chamber.

### Colonies Reading and Result Interpretation

13. The Colony Forming Units (CFU) of each plate are counted at the end of incubation time and reported on the final report.
14. The interpretation of the result is made according to the suggestions of the Clean Room or isolator producer or to the International Standards.

### Air Flow monitoring

15. The air flow of the instrument should be regular monitored every month by the operator using the “Pyramid” System to identify possible irregular operation.  
The air flow of the instrument should be every six months or twelve months (depending from the frequency of use) checked and recalibrated by an independent Agency or producer or distributor.

**Battery charge**

16. The operator should recharge the battery pack of the instrument using the appropriate battery charger.

- NON CONFORMITY

Examples:

- a. Low battery warning on the visual display ® Battery recharging
- b. The Contact plate is not very well fixed in the aspirating chamber of the air sampler ® Adjust the position of the 3 fixing feet
- c. The calibration certificate of the instrument is expired ® Contact the agency for an immediate re-calibration
- d. The body of the instrument fell down ® Check the functionality of the electronics and the air flow with the "Pyramid" System
- e. The "microbiological growth test" was negative ® Control the expiration date of the documentation of the medium
- f. The agar surface of the Contact plate touches the internal part of the aspirating head ® The used Contact plate is not correct or the volume of agar is in excess.
- g. The AISI stainless steel aspirating chamber has some corrosion ® Detergent or disinfectant using chlorine or other aggressive chemicals must be avoided
- h. The instrument commands are giving wrong reading on the visual display ® Check the cable connection and eventually ask for servicing



Pyramid - Code: 86666



Dispo-Head - Code: 86996

